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DEC 1 2 2011

Exhibit 2

510(k) Summary

The 2.5mm Diameter ARROW-LOK Implant and the ARROW-LOK Hybrid Implant as Additions to the ARROW-LOK Digital Fusion System

Submitted by:	Arrowhead Medical Device Technologies, LLC 328 Poplar View Lane East, Suite 2 Collierville, TN 38017
Date:	December 12, 2011
Contact Person:	Thomas J. Twardzik Vice President, Sales and Marketing Office: (901) 853-4366 Fax: (206) 222-9173 Email: Tom@ArrowheadDevices.com
Proprietary Name:	ARROW-LOK Digital Fusion System
Common Name	Intramedullary Bone Fastener
Device Classification Regulation	21 CFR 888.3040 (implants/instruments) – Class II
Device Product Code and Panel	HTY: Pin, Fixation, Smooth 87 Orthopedics
Device Description	The ARROW-LOK Digital Fusion device features a three dimensional arrow shape. The implants are available in multiple lengths with arrowheads of various diameters and in 2 different angles. The implant is manufactured from stainless steel and is designed for single use only.
Intended Use	The ARROW-LOK Digital Fusion System is indicated for fixation of osteotomies, arthrodeses and reconstruction in the lesser toes following corrective procedures. It is not intended for use in the spine.
Predicate Devices	Arrowhead Fixation Device (K100926) NEWDEAL, S.A. K-wire (K022599) Arthrex, Inc. K-wire (K052736)

Exhibit 2

510(k) Summary

The 2.5mm Diameter ARROW-LOK Implant and the ARROW-LOK Hybrid Implant as Additions to the ARROW-LOK Digital Fusion System

Technological Characteristics	The ARROW-LOK Digital Fusion System has similar technological characteristics when compared to the predicate devices. In addition, substantial equivalence was shown through Rotational Forces Testing, Pull-out Testing and Four-Point Bend evaluations. The evaluations confirmed that the ARROW-LOK Digital Fusion System is at least equivalent to the predicate devices.
Substantial Equivalence Information	The ARROW-LOK Digital Fusion System is similar to legally marketed devices including the Arrowhead Fixation Device, newdeal K-wire, and the Arthrex K-wire. The ARROW-LOK Digital Fusion System has similar indications for use and technological characteristics as these predicate systems. Device and performance evaluations confirmed that the ARROW-LOK Digital Fusion System is substantially equivalent to the newdeal K-wire. Therefore, the ARROW-LOK Digital Fusion System is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 12 2011

Arrowhead Medical Device Technologies, LLC
% Thomas J. Twardzik
Vice President, Sales and Marketing
328 Poplar View Lane East, Suite 2
Collierville, Tennessee 38017

Re: K112675
Trade/Device Name: ARROW-LOK Digital Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 13, 2011
Received: September 14, 2011

Dear Mr. Twardzik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 1

Indications for Use Statement

510(k) Number: K112675

Device Name: ARROW-LOK Digital Fusion System

Indications for Use: The ARROW-LOK implant is indicated for fixation of osteotomies, arthrodeses and reconstruction in the lesser toes following corrective procedures. It is not intended for use in the spine.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112675